ICS 11.040.10, 83.140.40 SLOVENSKÁ TECHNICKÁ NORMA Máj 2018

| STN | **Anestetické a dýchacie prístroje Nízkotlakové hadicové zostavy používané na medicinálne plyny (ISO 5359: 2014) Zmena A1** | **STN EN ISO 5359/A1**<br><br>85 2130 |
|---|---|---|

Anaesthetic and respiratory equipment - Low-pressure hose assemblies for use with medical gases (ISO 5359:2014)

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 04/18

Obsahuje: EN ISO 5359:2014/A1:2017, ISO 5359:2014/Amd 1:2017

**126395**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

# EN ISO 5359:2014/A1

November 2017

ICS 83.140.40; 11.040.10

English Version

# Anaesthetic and respiratory equipment - Low-pressure hose assemblies for use with medical gases - Amendment 1 (ISO 5359:2014/Amd 1:2017)

Matériel d'anesthésie et de réanimation respiratoire - Flexibles de raccordement à basse pression pour utilisation avec les gaz médicaux - Amendement 1 (ISO 5359:2014/Amd 1:2017)

Anästhesie- und Beatmungsgeräte - Niederdruck-Schlauchleitungssysteme zur Verwendung mit medizinischen Gasen - Änderung 1 (ISO 5359:2014/Amd 1:2017)

This amendment A1 modifies the European Standard EN ISO 5359:2014; it was approved by CEN on 16 August 2017.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for inclusion of this amendment into the relevant national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This amendment exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

**CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels**



Ref. No. EN ISO 5359:2014/A1:2017 E

**EN ISO 5359:2014/A1:2017 (E)**

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# European foreword

The text of this Amendment EN ISO 5359:2014/A1:2017 to the EN ISO 5359:2014 from Technical Committee ISO/TC 121 “Anaesthetic and respiratory equipment” of the International Organization for Standardization (ISO) has been taken over as an amendment to the European Standard by Technical Committee CEN/TC 215 “Respiratory and anaesthetic equipment” the secretariat of which is held by BSI.

This Amendment to the European Standard EN ISO 5359:2014 shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by May 2018, and conflicting national standards shall be withdrawn at the latest by November 2020.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive.

For relationship with EU Directive, see informative Annex ZA, which is an integral part of this document.

The following referenced documents are indispensable for the application of this document. For undated references, the latest edition of the referenced document (including any amendments) applies. For dated references, only the edition cited applies. However, for any use of this standard ‘within the meaning of Annex ZA, the user should always check that any referenced document has not been superseded and that its relevant contents can still be considered the generally acknowledged state-of-art.

When an IEC or ISO standard is referred to in the ISO standard text, this shall be understood as a normative reference to the corresponding EN standard, if available, and otherwise to the dated version of the ISO or IEC standard, as listed below.

NOTE The way in which these referenced documents are cited in normative requirements determines the extent (in whole or in part) to which they apply.

**Table — Correlation between normative references and dated EN and ISO standards**

| **Normative references as listed in Clause 2 of the ISO standard** | **Equivalent dated standard** | |
|---|---|---|
| | **EN** | **ISO** |
| ISO 1307:2006 | EN ISO 1307:2008 | ISO 1307:2006 |
| ISO 1402:2009 | EN ISO 1402:2009 | ISO 1402:2009 |
| ISO 8033:2006 | EN ISO 8033:2006 | ISO 8033:2006 |
| ISO 9170-1:2008 | EN ISO 9170-1:2008 | ISO 9170-1:2008 |
| ISO 14155:2011 | EN ISO 14155:2011 | ISO 14155:2011 |
| ISO 14971:2007 | EN ISO 14971:2012 | ISO 14971:2007 |
| ISO 15001:2010 | EN ISO 15001:2011 | ISO 15001:2010 |

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

## Endorsement notice

The text of ISO 5359:2014/Amd 1:2017 has been approved by CEN as EN ISO 5359:2014/A1:2017 without any modification.

# Annex ZA
(informative)

# Relationship between this European Standard and the essential requirements of Directive 93/42/EEC [OJ L 169] aimed to be covered

This European Standard has been prepared under a Commission's standardization request [M/023 concerning the development of European Standards related to medical devices] to provide one voluntary means of conforming to essential requirements of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices [OJ L 169].

Once this standard is cited in the Official Journal of the European Union under that Directive, compliance with the normative clauses of this standard given in Table ZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding essential requirements of that Directive and associated EFTA regulations.

NOTE 1 Where a reference from a clause of this standard to the risk management process is made, the risk management process needs to be in compliance with Directive 93/42/EEC as amended by 2007/47/EC. This means that risks have to be reduced 'as far as possible', 'to a minimum', 'to the lowest possible level', 'minimized' or 'removed', according to the wording of the corresponding essential requirement.

NOTE 2 The manufacturer's policy for determining acceptable risk must be in compliance with Essential Requirements 1, 2, 5, 6, 7, 8, 9, 11 and 12 of the Directive.

NOTE 3 This Annex ZA is based on normative references according to the table of references in the European foreword, replacing the references in the core text.

NOTE 4 When an Essential Requirement does not appear in Table ZA.1, it means that it is not addressed by this European Standard.

**Table ZA.1 — Correspondence between this European Standard and Annex I of Directive 93/42/EEC [OJ L 169]**

| Essential requirements of Directive 93/42/EEC | Clause(s)/subclause(s) of this EN | Remarks/Notes |
|---|---|---|
| 7.3 | 4.5.1, 4.7.2 | |
| 7.5 | 4.5.2, 6.1.6, 7.3, 2nd dash | First paragraph: first sentence covered.<br>Second paragraph: covered for phthalates.<br>Third paragraph: covered for phthalates in the Instructions for Use. |
| 7.6 | 6.3.1 | |
| 9.1 | 4.6.2.1, 4.6.7, 4.6.8, 4.6.9, 4.6.10, 4.6.11 | |
| 9.2, first and second indents only | 4.5.2, 4.5.4, 4.6.2, 4.6.3, 4.6.5 | Second indent covered for temperature and pressure |

| Essential requirements of Directive 93/42/EEC | Clause(s)/subclause(s) of this EN | Remarks/Notes |
|---|---|---|
| 9.3 | 4.5.1, 4.7.1, 4.7.2 | And via normative reference to ISO 15001 |
| 12.7.1 | 4.6.2, 4.6.3, 4.6.4, 4.6.5 | |
| 12.7.4 | 4.6.7, 4.6.8, 4.6.9 | |
| 12.8.1 | 4.6.4 | Covered for maintenance of flow when the hose is compressed |
| 13.2 | 6.2 | The use of colour codes of harmonised standards is mandatory in the EU. Covered for the use of gas-specific colour coding only. |
| 13.3 b) | 6.3.2 | |
| 13.3 e) | 6.1.5 | |
| 13.6 d) | 7.3 first dash | Covered for details of the nature and frequency of maintenance and calibration |
| 13.6 q) | 7.3, last dash | |

**WARNING 1 —** Presumption of conformity stays valid only as long as a reference to this European Standard is maintained in the list published in the Official Journal of the European Union. Users of this standard should consult frequently the latest list published in the Official Journal of the European Union.

**WARNING 2 —** Other Union legislation may be applicable to the products falling within the scope of this standard.

# INTERNATIONAL STANDARD

# ISO 5359

Fourth edition
2014-10-01

**AMENDMENT 1**
2017-07

# Anaesthetic and respiratory equipment — Low-pressure hose assemblies for use with medical gases

## AMENDMENT 1

*Matériel d'anesthésie et de réanimation respiratoire — Flexibles de raccordement à basse pression pour utilisation avec les gaz médicaux*

*AMENDEMENT 1*

Reference number
ISO 5359:2014/Amd.1:2017(E)



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# Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 1, *Breathing attachments and anaesthetic machines.*

# Introduction

This document has been prepared in response to the revision of ISO 7396-1, which applies in its third edition also to oxygen supply systems in which all sources of supply deliver oxygen 93. Following this decision, ISO/TC 121/SC 1 approved developing the 1st amendment to ISO 5359:2014 by replacing the term “oxygen-enriched air” by “oxygen 93” and by introducing the designation “$O_2$ 93” for the medical gas oxygen 93.

ISO 5359:2014/Amd.1:2017(E)

# Anaesthetic and respiratory equipment — Low-pressure hose assemblies for use with medical gases

## AMENDMENT 1

*Page 1, Scope*

Replace the text of the 8th list item that currently reads “oxygen-enriched air” by “oxygen 93”.